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EXAMINER	
HUPCZEY, JR, RONALD JAMES	

ART UNIT	PAPER NUMBER
3739	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,229	EISELE, FLORIAN	
	Examiner	Art Unit	
	RONALD J. HUPCZEY, JR.	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/22/2006, 1/30/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. In response to the preliminary amendment filed August 2nd, 2006, claims 1-17 are currently pending with claims 1-15 amended and claims 16-17 newly added. The following is a complete response to the August 2nd, 2006 communication.

Claim Objections

2. Claim 13 is objected to because of the following informalities: For the sake of increasing the clarity of the claim, the examiner recommends that applicant amend the claim to read in line 3 -- inner layer, liquid-- and in line 4 -- outer layer, liquid--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. With regard to the limitation of "... interior space is enclosed … electrically conductive liquid...", the specification sets forth (see pages 18 and 19, paragraph [0061]) an interior space hydraulically separated from the conductive fluid by an expandable auxiliary body which is completely water-tight, but fails to provide support for an expandable body which is hydraulically separated from the conductive liquid. The

expandable auxiliary body as disclosed in the specification directly interacts with the electrically conductive fluid.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 13, the recitation therein of "...the surface direction." is unclear and confusing. It is unclear if the surface's direction refers to a direction of expansion of the surface, the orientation of the surface to the surrounding tissue or the just the orientation of the surface itself. For the purposes of examination, the examiner is interpreting the claim as the liquid in the outer layer being conducted in a direction perpendicular to the orientation of the surface.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 6-13 and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Swanson et al (US Pat. No. 5,797,903).

Regarding claim 1, Swanson discloses an apparatus (system **10**) containing a three-dimensional body (electrode body **20**) which can be expanded to various states of expansion (see col. 5; 12-18) and at least one electrode (electrode body **20** in conjunction with electrode **30**)

capable of conducting an HF coagulation current into tissue wherein the electrode forms at least portion of the three-dimensional body and wherein by one of continuous or stepwise expansion of the body, the electrode can be kept in constant electrical contact with the tissue during coagulation.

Regarding claim 6, Swanson discloses the electrode to be comprised of a treatment electrode (electrode body **20**) which is at least partially permeable to liquid (via pores **44**) and which can be brought into contact with a section of tissue. Swanson further discloses a liquid-supply device (lumen **34**, port **36**) through which electrically conductive fluid can be delivered to the treatment electrode and a current supply device (radio frequency generator **40**, signal wire **32**) capable of delivering the HF coagulation current to the treatment electrode in such a way that HF treatment current is conducted to the liquid which is passing through the treatment electrode (see col. 6; 15-26).

Regarding claim 7, Swanson discloses the treatment electrode to consist of an elastically stretchable or an unfoldable surface element which defines an interior space to which an internal pressure can be applied to expand the surface element via the increase of internal pressure (see col. 5; 12-18).

Regarding claim 8, Swanson discloses the surface element to be in the form of a sphere (see figures 2-4).

Regarding claim 9, Swanson discloses the treatment electrode to be constructed in the form of a balloon catheter (see figures 2-4).

Regarding claim 10, Swanson discloses the interior space to be capable of being filled with an electrically conductive liquid (see col. 5; 11-18).

Regarding claim 11, Swanson discloses the electrically conductive fluid to be comprised of a viscosity modifying substance (see col. 11; 53-59).

Regarding claim 12, Swanson discloses the treatment electrode to be made of a thermally stable material in the form of a film, felt or woven fabric (see col. 7; 66 – col. 8; 34).

Regarding claim 13, Swanson discloses the interior space to be enclosed by an expandable body (bladder **64**) and for the surface element to be constructed in several layers (inner layer; bladder **64** and outer layer: electrode body **20**) wherein the liquid can be directed from the inner layer toward the outer surface and from the outer layer in a direction perpendicular to the orientation of the surface (see col. 18; 44-57).

Regarding claim 15, Swanson discloses electrode capable of being supplied with a cutting current (electrode body **20** in conjunction with electrode **30**). The examiner notes that applicant has claimed statements of intended use, i.e. "adapted to be supplied with a cutting current". Such limitations fail to structurally distinguish the claims from the prior art of record, which is capable of being used as desired. Since the prior art structure is capable of performing the intended use, then it meets the claim.

Regarding claim 16, Swanson discloses the thermally stable material to consist of tetrafluoroethylene (see col. 7; 66 – col. 8; 5).

9. Claims 1, 6 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Koblish et al (US Pat. No. 6,837,885 B2).

Regarding claim 1, Koblish discloses an apparatus containing a three-dimensional body (inflatable therapeutic element **14**) which can be expanded to various states of expansion and at least one electrode (electrode **32**, porous region **26**) capable of conducting an HF coagulation

current into tissue wherein the electrode forms at least portion of the three-dimensional body and wherein by one of continuous or stepwise expansion of the body, the electrode can be kept in constant electrical contact with the tissue during coagulation (see col. 10; 9-30).

Regarding claim 6, Koblish discloses the electrode to be comprised of a treatment electrode (porous region **26**) which is at least partially permeable to liquid (via micropores **28**) and which can be brought into contact with a section of tissue (see figure 3). Koblish further discloses a liquid-supply device (fluid supply device **72**) through which electrically conductive fluid can be delivered to the treatment electrode and a current supply device (control apparatus **41**) capable of delivering the HF coagulation current to the treatment electrode in such a way that HF treatment current is conducted to the liquid which is passing through the treatment electrode (see col. 7; 36 - col. 8; 8).

Regarding claim 14, Koblish provides a suction device (fluid delivery device **72** in conjunction with ventilation lumen **58**) to such away liquid.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al (US Pat. No. 5,707,903).

Regarding claim 17, Swanson fails to specifically recite the limitation of a partition layer placed in between the inner layer and outer layer. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form the three-dimensional body of a plurality of layers with each layer suited, as evidenced by Swanson (see col. 8; 50-63), to provide for a desired level of liquid perfusion and to create a structure which is capable of withstanding an desire amount of internal inflation pressure while not ripping or tearing.

13. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al (US Pat. No. 5,797,903) as applied to claim 1 above, and further in view of Lennox et al (US Pat. No. 5,545,195).

Regarding claim 5, Swanson discloses a liquid-supply device (lumen **34**, port **36**) through which electrically conductive fluid can be delivered to the treatment electrode but fails to disclose a measurement device to detect the state of expansion of the three-dimensional body. Lennox discloses an analogous device containing a three-dimensional body which can be expanded to a plurality of expanded states containing at least one electrode. Lennox further discloses a measurement device to detect the state of expansion of the three-dimensional body (syringe **224** and its displacement, see col. 4; 2-12). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide such a fluid supply and monitoring device as that of Lennox in conjunction with the device of Swanson in order to

both provide fluid to the three-dimensional body of Swanson and adequately assess the level of expansion of the three-dimensional body. Additionally, the provision of monitoring the expansion of the three-dimensional body of a device as Swanson and Lennox is well known in the art and such monitoring ensures the three-dimensional body is expanded to a safe level, not exposed to excessive amounts of pressure and does not apply excess pressure to the body lumen or space in which it is inserted.

14. Claims 2, 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koblish et al (6,837,885 B2) as applied to claim 1 above, and further in view of Abele et al (5,496,311).

Regarding claim 2, Koblish discloses a control device (control apparatus **41**, fluid supply device **72**) functioning to monitor and control coagulation current as well as controlling the expansion of the body to maintain an adequate level of contact (see col. 8; 9-30 and col. 9; 52 - col. 10; 26). Koblish further discloses the control apparatus to function via measurement of fluid temperatures internal to the body via a thermistor (see col. 8; 9-22). Koblish fails to specifically detail the controlling of the degree of expansion of the body dependent on the coagulation current. Abele discloses a similar expandable system consisting of a three-dimensional body consisting of at least one electrode (see figure 3). Abele further discloses the controlling of the coagulation current by the monitoring of the temperature of the fluid internal the body (see col. 9; 42-53) and various levels of control of the pressure and volume of fluid within the body (see col. 9; 54 - col. 10; 4). Additionally Abele discloses the assessment of contact between the body and a target portion of tissue to be capable of being assessed by the change in power it requires to maintain a given temperature of fluid with a body (see col. 13; 57 - col. 14; 2) and the subsequent control of the system based on the change in power sensed. Therefore, it would have

been obvious to one of ordinary skill in the art at the time the invention was made to provide a control device and fluid control system such as that of Abele in conjunction with the device of Koblish to provide for a device which controls the expansion if the body dependent on the coagulation current. The establishing and maintaining of contact in such RF procedures is well known to prevent the charring of tissue and to effectively convey the energy transmitted to the conductive fluid into the target tissue. Furthermore, as evidenced by Abele, the maintaining of a desired level of contact can effectuate control over the depth of heating in a target portion of tissue and reduce if not stop the blood flow in the target area thereby reducing the amount of cooling caused by the flow.

Regarding claim 3, Koblish discloses the control device adapted to enable the adjustment of the current density of the coagulation current between the electrode and tissue (see col. 8; 9-30).

Regarding claim 4, Koblish discloses the control device permitting the current density and state of expansion to be adjusted independently (fluid supply device **72** and control apparatus **41**) such as the fluid supply device maintaining a constant volume and the control apparatus functioning on power control via sensed values from the thermistor.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD J. HUPCZEY, JR. whose telephone number is (571)270-5534. The examiner can normally be reached on Mon. - Fri. from 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/RONALD J HUPCZEY, JR./
Examiner, Art Unit 3739

/Linda C Dvorak/
Supervisory Patent Examiner, Art Unit 3739

RJH